

REMARKS

After entry of this response, claims 22, 29, 30, 36, 42, 43, 46, 47, 54, and 55, remain pending in the present application and no new claims added to the application. Claim 44 has been cancelled to avoid duplication with other amended claims. Applicants appreciate Examiner's offer during the interview of May, 24, 2005, to rejoin the withdrawn and related method claims if the pending claims are found allowable and would be happy to help identify the proper method claims to rejoin. Applicants intend for this response to also serve as documentation of the substance of the interview conducted on May 24, 2005 and respectfully requests reconsideration by the Examiner in light of the following remarks.

Claim Objections

The Examiner objected to claims 22, 44, 46, and 47 as depending from unelected claims. Claim 44 has been cancelled and claims 22, 46, and 47 have been amended to no longer depend from unelected claims.

Restriction Requirement

Applicants provisionally withdraw claims 45 and 48-53 in accordance with Examiner's restriction requirement with traverse on the grounds that no serious burden on the Examiner exists.

Claim Rejections

Swan '075 does not anticipate or make obvious claims 54 and 55.

The Examiner rejected claims 54 and 55 under 35 U.S.C. § 102(b) or, in the alternative, under 35 U.S.C. § 103(a) as being anticipated or obvious over U.S. 4,414,075 to Swan et al. ("'075"). The Examiner correctly notes that these product-by-process claims are only patentable if the product is a patentably distinct article.

The process of the '075 patent involves attaching a reagent to a surface and then attaching a target molecule to the reagent. These target molecules may be polymers or bioactive agents, for example. Generally speaking and for purposes of this comparison only, the coatings claimed herein are formed by attaching a reagent to a surface and then using that reagent to initiate polymerization of monomers subsequently applied to the reagent coated surface, thereby forming the desired coating. The coating can be said to “grow” from the surface. These different processes result in coatings that are structurally different, as discussed below.

The products described in claims 54 and 55 are patentably distinct over products disclosed in the '075 because the coatings can be thinner, the coating molecules can be more densely attached to the surface, there can be minimal or no crosslinking in the coating, and the coating characteristics (e.g., texture and thickness) can be controlled more closely and accurately.

Applicants describe distal protection devices for use in filtering blood *in situ* downstream from an intervention site. Page 5, lines 9-14. These devices, and other medical devices, have particularly small pores or apertures that are intended to remain open and unclogged in the course of their intended use. The coatings of the '075 and similar prior art coatings that are formed by attaching a reagent to a surface and then attaching a target molecule to the reagent may be unsuitable for these and other applications due to the thickness of the resultant coating and the tendency for “webbing” to occur across the pores or apertures of the device. These thickness and webbing issues may be caused by the larger original size of the target molecules that are immobilized in prior art processes and or the associated steric hindrance between these larger molecules. Also, the *in situ* grafting of claims 54 and 55 where monomers may be added in a molecule by molecule fashion as compared to, the random nature of the prior art

immobilization, i.e. where a long chain polymer may be attached to the reagent at any point along the chain, results in coatings that are structurally distinct in unobvious ways for the prior art coatings.

A second structural difference between the coatings of claims 54 and 55 and the prior art coatings is the density of polymer that can be attached to the surface. Page 8, lines 9-13. In the prior art processes cited in this rejection, a reagent is attached to a surface and relatively large target molecules are immobilized by the reagent. These relatively large target molecules interfere with each other through steric hindrance or attach to more than one reagent site limiting the amount of polymer or target molecule that can be immobilized by the reagent and potentially inhibiting the formation of a dense and uniform coating. The coatings of claims 54 and 55 are formed by *in situ* polymerization of relatively small molecules, allowing more efficient utilization of the reagent in coating the surface.

Coatings of claims 54 and 55 may have less crosslinking than prior art coatings due to the formation of linear polymer chains as compared to the crosslinked matrix that results from the reagents attaching to relatively large target molecules. The generally uncrosslinked nature of the coatings of claims 54 and 55 provide for a thin conformable coating unachievable by prior art processes that are useful in many applications requiring such coatings, i.e., distal protection devices. These characteristics, and others, are novel and non-obvious structural differences in the coatings, structural differences that result directly from the differences in the process that have been acknowledged by the Examiner. Applicants believe their burden of showing nonobvious structural differences between the claimed product and the prior art product has been met, and that claims 54 and 55 are in condition for allowance.

Swan '698 in view of Swan '075 does not render obvious claims 22, 29, 30, 36, 42, 43, 46, 47, 54, or 55.

The Examiner rejected claims 22, 29, 30, 36, 42, 43, 46, 47, 54, and 55 as being obvious over U.S. 6,077,698 to Swan ('698) in view of the '075. Swan '698, like Swan '075, discloses the immobilization of target molecules by reagents that are covalently attached to a surface. Swan '698 does not teach or suggest a support surface bearing a polymeric coating as in claims 22, 46, and 47; a porous support surface bearing a polymeric coating as in claims 29, 30, 54, and 55; or a device comprising a surface bearing a polymer coating as in claims 36, 42, 43.

The articles of the subject claims are patentably distinct in light of the articles of Swan '698 as modified by Swan '075 for at least the reasons that the articles of claims 54 and 55 are distinct over Swan '075 as just discussed. Swan '698 as modified by Swan '075 does not disclose or make obvious the coatings of the subject claims, which can be thinner, the molecules of the coating can be more densely attached to the surface, there can be minimal or no crosslinking in the coating, and the coating characteristics can be controlled more closely and accurately.

Swan '994 in view of Swan '698 and Swan '075 does not render obvious claims 22, 29, 30, 36, 42, 43, 46, or 47.

Applicants submit with this response the Affidavit of Dale G. Swan, one of the inventors of the subject application and the first-named inventor of all of the art cited in this Office Action. The Affidavit is incorporated by reference into this response in full. As explained in the Affidavit of Dale G. Swan, reagents including positively charged substituents were not considered as viable options when developing the inventions disclosed in the '994 patent, but

have since been found to provide benefits such as better wetting of certain surfaces during the grafting process and improved alignment of certain monomers, that distinguish them from negatively charged reagents. Therefore, the Affidavit describes the development of “grafting reagent” technology and the fact that the subject matter of claims 22, 29, 30, 36, 42, and 43 having the positively charged substituents was not obvious to one of skill in the art based on the teachings of the cited references.

Claims 46 and 47 require a nonpolymeric grafting reagent having four photoinitiator groups attached to a nonpolymeric core molecule. The Office Action cites claim 28 of the '994 patent as disclosing such a species, but claim 28 only describes “a coating agent comprising *two or more* photoreactive species.” Column 31, Lines 2-3. This open ended claim language does not disclose or make obvious the grafting reagents used to create the support surface of claims 46 and 47. The reagents disclose in the '994 patent all have fewer than four photoreactive groups and therefore the cited references do not disclose or make obvious grafting reagents with four or more or surfaces formed using such reagents.

The reagents having four photoreactive groups have demonstrable benefits over the reagents of the '994 patent. These reagents can attach more securely to a surface by having more than one photoreactive group attached to the surface while still having groups available to initiate polymerization of monomers and formation of a coating. These reagents can also attach to the surface like a jack from a child's game leaving one photoreactive group exposed in an essentially perpendicular orientation to the surface for more effective initiation and coating formation. The steric hindrance of the four groups can also help to ensure that a group is always available to initiate polymerization whereas other reagents with only two photoinitiators may attach to a surface at both ends frustrating the coating process.

Swan '994 in view of Swan '698 and Swan '075 does not render obvious claims 54 and 55.

Claims 54 and 55 are patentable over the cited references for at least the same reasons discussed above relative to claims 46 and 47. That is, none of the cited references disclose or make obvious the use of a reagent having four or more photoinitiator groups attached to a nonpolymeric core molecule to form the claimed support surface.

Double Patenting

Applicants believe that claims 22, 29, 30, 36, 42, 43, 46, 47, 54, and 55 are not unpatentable under obviousness-type double patenting in light of claims 28, 29, and 33 of the '994 patent in view of the other Swan references. This is true at least because the cited claims of the '994 patent require a negatively charged substituent that is not required by any of the claims at issue. As discussed previously, reagents with negatively charged substituents do not make obvious the reagents of the claims at issue. Since claims 28, 29, and 33 of the '994 patent require negatively charged substituents, the claims at issue are not obvious in light of those claims and the public policy concern of unjustified or improper timewise extension of patent rights is not implicated.

Applicants have amended certain claims solely to advance the prosecution of this application and to obtain allowance on allowable claims at the earliest possible date. Therefore, no admission may be inferred from the amendments to the claims herein and Applicants reserve the right to prosecute originally filed claims in later continuing applications.

In view of the foregoing, it is submitted that this application is in condition for allowance. Favorable consideration and prompt allowance of the application are respectfully requested.

If the Examiner believes that an Examiner's amendment would put this application in condition for allowance or would like to discuss this submission for any reason, Applicants

would welcome the Examiner's input and respectfully request a telephonic interview. The Examiner may contact the undersigned at (612) 492-7305 to schedule such an interview if necessary.

Respectfully submitted,



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